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Statens legemiddelverk

OTC use in Norway for naproxen, ATC-code: M01AE02

- This OTC substance report is based on the assessment of the OTC indication and posology for products containing naproxen. It defines the preferred Norwegian wording for the package leaflet and labelling for OTC products containing naproxen. In addition, an overview of the approvable strength(s), pharmaceutical form(s) and pack size(s) exempt from medical prescription in Norway is included.

- The proposed OTC indication and posology in the OTC package leaflet and labelling must be covered by the information approved in the corresponding SmPC.

Preparations for oral use, up to 250 mg strength per unit

1. Package leaflet

1.1 Indication

Til voksne og barn over 40 kg (12 år): korttidsbehandling av milde til moderate smerter som hodepine, tannpine, menstruasjonssmerter og muskel- og leddsmerter.

1.2 Posology

Change the quantity from the given strength to the number of entities to be taken (e.g. 1–2 tablets, 1 suppository, 20 ml…).

Voksne og barn over 40 kg (12 år): 250 mg–500 mg som startdose. Deretter 250 mg ved behov. Ikke ta mer enn 750 mg i døgnet.

Kontakt lege etter 5 dager hvis plagene blir verre eller ikke blir bedre.

2. Labelling

2.1 Indication

State the indication as in the PIL. If the full indication is stated on the back panel of the package, the following abbreviation can be used on the front panel:

Smertestillende

2.2 Posology

State the dosage as in the PIL. However, shortened if needed.

2.3 Other information

Skal ikke brukes av personer som har magesår, eller dersom acetylsalisylsyre, ibuprofen eller andre smertestillende og febernedsettende legemidler har forårsaket astma eller allergiske reaksjoner.

3. Content of the pack

The table below presents the highest level of the terms for approvable pharmaceutical forms, if possible. For example: the term "tablets" includes all types of tablet formulations as for example film coated tablets or chewable tablets. For active substances where some pharmaceutical forms are exempt from approval due to safety concern, this is stated explicitly below the table.

Pharmaceutical form	Maximum strength	Maximum pack size
Tablets, capsules, oral suspension or granules in sachets	250 mg	20